



## Agenda-EU-Innovation Network workshop with academia

16 November 2018, 09:00-16:00, meeting room: 2A

Co-Chairs: Marisa Papaluca (EMA) and Esa Heinonen (FIMEA)

		Speaker	
09:00	Welcome address	Guido Rasi, EMA	
09:10	Introduction	All	
Session 1: Setting the scene			
09:30	The role of EMA in promoting innovation	Marisa Papaluca Amati, EMA	
09:45	What is the EU-Innovation Network	Esa Heinonen, FIMEA	
10:00	New clinical trial regulation and clinical research in academia	Elke Stahl, BfArM, Clinical Trials Facilitation Group chair	
10:30	Q&A		
10.45	Coffee break		
Session 2: EU funded initiatives			
11:00	The STARS project	Wiebke Loebke, BfArM	
		Julia Stingl (via TC), BfArM	
11:20	EU infrastructures: what they can offer		
	• EATRIS	David Morrow	
	• ELIXIR	Serena Scollen	
	• BBMRI	Francesco Florindi	
	• ECRIN	Jacques Demotes	
12:00	DG RTD perspective	Stéphane Hogan	
12:20	Q&A		
12:45	Lunch break		



		Speaker	
Session 3: Experience and needs of the research centres			
13:30	Break-out sessions:	Group A	
	The biggest challenges of carrying out academic clinical	Group B	
	studies	Group C	
	<ul> <li>Experiences on dealing with national regulatory authorities (scientific advice, clinical trial applications, GXP inspections etc.)</li> </ul>		
	<ul> <li>Needs for training/interaction on regulatory guidelines and processes</li> </ul>		
	Training available at national level on regulatory science		
14:30	Reports from the break-out sessions	Rapporteur Group A	
		Rapporteur Group B	
		Rapporteur Group C	
15:15	General discussion	All	
15:50	Conclusions and way forward	Marisa Papaluca Amati, EMA	
16:00	End of the meeting		